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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,598	03/01/2002	Donald J. Carano	P-3458C1	7673
7590 03/01/2004				
CASELLA & HESPOS LLP				
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274 Madison Avenue				
New York, NY 10016				
EXAMINER				
MUSSEY, BARBARA J				
ART UNIT		PAPER NUMBER		
1733				

DATE MAILED: 03/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,598

Applicant(s)

CARANO, DONALD J.

Examiner

Barbara J. Musser

Art Unit

1733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai in view of Newby et al.(U.S Patent 6,017,317), Wermund, and Knowles.

Kasai discloses an evacuated blood collection tube which is sealed at one end with a seal comprising a sealing member attached to a stopper(45).(Figure 5) While Kasai discloses the sealing member is made from a layer of PET with a metal foil attached thereto which is attached to an adhesive layer(Col. 8, ll. 8-13), it does not disclose that the metal foil is between the PET and the adhesive. It is well-known and conventional in the blood tube arts to orient the seal such that the metal foil is between the PET and the adhesive as shown for example by Newby et al. which discloses the sealing member has the metal foil between the PET and the adhesive.(Col. 3, ll. 56-65) It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the seal such that the metal foil is between the PET and the adhesive since this is well-known and conventional in the art as shown for example by Newby et al.(Col. 3, ll. 56-65)

Kasai suggests the use of an adhesive to bond the sealing member to the stopper(Col. 8, ll. 17) but is silent as to the specifics of the formation process. Wermund

Art Unit: 1733

discloses forming closures for containers made of a sealing member and a base(a portion that fits into the container), by placing the sealing member in an injection mold and injecting material to form the base to securely bond the seal and base together,(Col. 5, ll. 2-7) but does not disclose a continuous process forming multiple items at the same time.

Knowles discloses making closures in a continuous process wherein a web of material from a roll is placed in a mold, and material is injection molded to form the closure. The closures are then cut from the web of material.(Figure 1; Col. 4, ll. 35-Col. 5, ll. 10) It is noted that the sealing members of Kasai have larger diameters than those of the stoppers.(Col. 8, ll. 29-33)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the metal foil of the sealing member between the PET and the adhesive since this is well-known and conventional in the art as shown for example by Newby et al.(Col. 3, ll. 56-65), to form the seal of Kasai by injection molding the stopper onto the sealing member since this would securely bond the two together(Wermund; Col. 5, ll. 2-7), and to make this a continuous process as shown by Knowles(Col. 1, ll. 56-64) since this would increase production as is well-known in the art. It is noted that Kasai indicates the stopper and sealing member have diameters, indicating they are circular(Col. 8, ll. 28-33), and Figure 4 indicates the sealing member is planar.

Regarding claim 6, Kasai does not disclose the specific adhesive layer which bonds the metal foil to the top of the blood collection tube. Newby et al. discloses the

Art Unit: 1733

adhesive can be PET.(Col. 3, ll. 56-60) It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any conventional adhesive which is known to be used to bond metal to glass or plastic such as PET, particularly since Newby et al. discloses PET can be used as the adhesive.

3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai, Newby, Wermund, and Knowles as applied to claim 1 above, and further in view of Dawson(U.S. Patent 4,445,836).

The references cited above do not disclose winding the seals on a roll before cutting them from the sealing material. Dawson discloses forming a string of injection molded articles which are wound in a coil so that they can be used in an automated assembly process.(Abstract) It would have been obvious to one of ordinary skill in the art at the time the invention was made to wind the web of preformed seals into a roll and cut later since this would greatly facilitate its use in an automated assembly process(Abstract) in the process of making the container lid as set forth by Kasai, Newby, Wermund, and Knowles.

4. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai, Newby, Wermund, and Knowles as applied to claim 1 above, and further in view of Miller(U.S. Patent 6,039,698).

The reference cited above do not disclose the seal having an outer cap with a skirt which extends down the tube having an annular shoulder extending inward with an aperture at the center. Miller discloses a seal having an outer cap with a skirt which extends down the tube having an annular shoulder extending inward with an aperture at

Art Unit: 1733

the center and a collar extending upward from the aperture.(Figure 5) It would have been obvious to one of ordinary skill in the art at the time the invention was made to attach the cap of Miller on the seal of Kasai, Wermund, and Knowles since this cap would allow separation of the seal from the tube of Kasai while reducing the risk of the technician removing the seal contacting the blood within the tube.(Col. 1, ll. 65- Col. 2, ll. 6)

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kasai, Newby, Wermund, Knowles, and Miller as applied to claim 7 above, and further in view of Yamazaki et al.(U.S Patent 5,326,534).

The references cited above do not disclose a top stopper within the collar extending upward from the aperture of Kasai, Newby, Wermund, Knowles, and Miller. Yamazaki et al. discloses a method of sealing blood tubes wherein a rubber stopper is applied to the top of the sealing member.(Figure 1) It would have been obvious to one of ordinary skill in the art at the time the invention was made to apply a top stopper to the sealing member of Kasai, Wermund, Knowles, and Miller to help insure the seal re-sealed after use.(Col. 3, ll. 8-14)

Response to Arguments

6. Applicant's arguments filed 12/3/03 have been fully considered but they are not persuasive.

7. In response to applicant's argument that Wermund and Knowles are nonanalogous art, it has been held that a prior art reference must either be in the field of

Art Unit: 1733

applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, they are in applicant's general field of endeavor, i.e. forming a cap for a container which is intended to seal the container. The methods of forming lids are the same, whether the lid is intended to seal a glass container holding blood, or a plastic container holding food. Both require a lid that seals tightly and does not allow the contents to escape. While they use different types of materials, the same purpose is served. Additionally, one would have been led to look to these references for means to form the container lid, as the references to Kasai and Newby do not express a method for making the container lids in a continuous and cost effective manner.

Regarding applicant's argument that using the process of Knowles would deform and damage the metal layer, examiner is not suggesting the exact process of Knowles be used as it would not form the stoppers of Kasai desired. Rather, examiner is suggesting that the process of Knowles be used to modify the process of Kasai and Wermund since it shows how to form a number of container caps simultaneously.

Regarding applicant's argument that the references do not teach affixing the sealing member to the shoulder of the safety collar so that the PET faces away from the shoulder, Kasai discloses the first layer is the outermost layer. Therefore it would face the shoulder, and the innermost layer, applicant's PET layer, would face away from the

Art Unit: 1733

shoulder. Kasai also shows the stopper is spaced from the collar since the stopper fits inside the test tube and the safety collar is on the outside.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Barbara J. Musser** whose telephone number is **(571) 272-1222**. The examiner can normally be reached on Monday-Thursday; alternate Fridays.

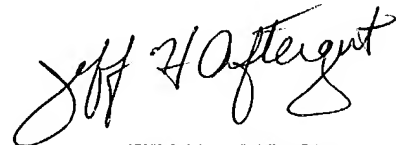
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571)-272-1226. The fax phone

Art Unit: 1733

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


BJM


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